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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,727	10/10/2006	Yechiel Shai	2488.031	8544
23405 7590 01/16/2008 HESLIN ROTHENBERG FARLEY & MESITI PC 5 COLUMBIA CIRCLE ALBANY, NY 12203			EXAMINER LUKTON, DAVID	
			ART UNIT 1654	PAPER NUMBER
			MAIL DATE 01/16/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,727	SHAI ET AL.	
	Examiner	Art Unit	
	David Lukton	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above claim(s) 8, 11-14 and 16-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4 and 5 is/are rejected.
- 7) ☐ Claim(s) 2, 3, 6, 7, 9, 10 and 15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Applicants' election (11/21/07) of Group 1 without traverse is acknowledged. However, applicants have mischaracterized the elected group. The elected ground does not "include" SEQ ID NOs: 1-46; rather, the elected group consists of SEQ ID NOs: 1-46. Second, the elected ground does not encompass cyclic analogs of lipophilic conjugates (other than SEQ ID NOs: 40-46 *per se*).

Also acknowledged are the specie/subgenus elections, i.e., the elected peptide is that of SEQ ID NO:10, i.e., the following (Xaa = D-Ala):



and the activity exhibited by this peptide is antibacterial.

Pursuant to the restriction claims 18-55 are withdrawn from consideration. In addition, claims 8, 11-14, 16, 17 are withdrawn, as they do not encompass the elected compound. Claims 1-7, 9, 10, 15 are examined in this Office action.



The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this action.

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the

United States.

Claims 1, 4, 5 are rejected under 35 U.S.C. §102(b) as being anticipated by Avrahami (*Biochem* **41**, 2254-63, 2002).

Avrahami discloses (page 2257, top of col 2) that palamitic and undecanoic acid conjugates of magainin inhibit fungal growth.

Thus, the claims are anticipated.

✦

Claims 1 and 4 are rejected under 35 U.S.C. §102(b) as being anticipated by Bouchaudon (USP 3,817,973).

Bouchaudon discloses (col 1, line 5+) compounds of the following formula (which are cyclized):

A-X-Dab-Thr-Dab-Dab-Dab-Y-Z-Dab-Dab-Thr

The compounds are asserted (col 5, line 24+) to exhibit antibacterial activity

Thus, the claims are anticipated.

✦

Claims 1 and 4 are rejected under 35 U.S.C. §103 as being unpatentable over Morytko (USP 7,262,268).

Morytko discloses (e.g., those in cols 65-66) various antibacterial peptides that bear an acyl

group.

Consider what instant claim 1 requires. The claim requires that the peptide have at least two amino acid side chains that are sufficiently basic to become protonated. The assumption is that this refers to the peptide *per se* (prior to conjugation) rather than to the conjugated peptide. This particular condition is met by either of the two peptides presented in cols 65-66 of the reference. Next, instant claim 1 recites that the peptide have a net positive charge that is at least +1. However, this limitation is not particularly meaningful in the absence of a pH. Given that the pH of the stomach is about 3 or less, it would have been obvious to one of ordinary skill that the carboxyl groups would become protonated if the compound were taken orally.



Claims 1 and 4 are rejected under 35 U.S.C. §103 as being unpatentable over Hill (USP 6,794,490).

Hill discloses (e.g, claim 4 of the patent) various antibacterial peptides that bear an acyl group. The explanation given above (the §103 over Morytko) applies here as well.



No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached at (571)272-0562. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

A handwritten signature in black ink, appearing to read "D. Lukton". The signature is fluid and cursive, with the first letter "D" being large and prominent.

DAVID LUKTON, PH.D.
PRIMARY EXAMINER